Commercial in Confidence

Online Registry for UCL Centre for Obesity Research and Obesity Research Biobank Syndicate

Proposal submitted by inidus limited

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Executive Summary

inidus propose to deliver a secure online registry using a proven openEHR Clinical Data Repository to support the Obesity Registry proposal by the UCL Centre for Obesity Research headed by Professor Rachel Batterham and the Obesity Research Biobank Syndicate.

The Registry will allow the Project to securely enter and store registry data in an open, sharable and computable form and easily export relevant dataset for analysis.

inidus have unique and substantial experience in the use of openEHR with a team with over 70 years digital health experience and strong clinical, informatics and business skills. inidus are able to rapidly deliver a robust solution based on a proven approach that is easily extensible to meet future needs.

Requirements

The proposal (replicated in Appendix A) by the UCL Centre for Obesity Research provides the dataset for the Registry.

The dataset creates between 150 and 200 separate data points, depending on the granularity of the data to be captured and stored. This is subject to further discussion, but has little impact on the overall proposal.

UCL Centre for Obesity Research wish to create an online Registry able to securely store patient data in a form that will make it available for analysis.

UCL Centre for Obesity Research require a simple data entry front end that will allow researchers and clinicians to manually enter data into the Registry.

UCL Centre for Obesity Research require a flexible mechanism to allow data in the Registry to be queried and exported in a computable form for analysis in an appropriate statistical package.

Proposed Solution

inidus propose a solution based on openEHR, a widely used open standard enabling the rapid development of interoperable EHR systems based on technology- and vendor-independent open source clinical models (archetypes).

Our solution has the following elements:

openEHR Registry

inidus propose the use of an openEHR Clinical Data Repository (CDR) hosted on the inidus platform supported by NHS cloud-hosting experts UK Cloud. [1]

Clinical Modelling

In order to support the UCL Obesity dataset it is necessary provide suitable information models. inidus has analysed the information provided and identified the extent to which existing models can be used and where additional model development is required. We propose to develop the required additional models as part of this work.

[1] **A separate conversation about making use of an existing CDR managed by North Thames Genomics Medicine Centre and University College London Hospital for some of the data is currently taking place, but it is assumed that inidus will be required to provide platform services for this project.**

Once the relevant models have been created they can be immediately used to store data in the CDR without any further engineering and make the data immediately queryable by openEHR's powerful query language. The use of openEHR data models ensures that data is interoperable, transportable and easily sharable and that UCL Centre for Obesity Research are not locked into to a particular technology or vendor. UCL Centre for Obesity Research remains in control of the data and the models used to define the dataset, which can be modified and adapted in the future without further engineering.

Data Entry Screens

In addition to the necessary modelling work inidus will also create data entry screens for each of the seven elements of the data set identified above. These screens will allow clinicians and researchers to enter, edit and review data for patients participating in the Registry project.

Data Query and Export

We assume that UCL Centre for Obesity Research will wish to export data from the registry for analysis using statistical tools. inidus will provide an easy export option for the required extract(s) - It should be noted that these exports are provided for convenience only and UCL Centre for Obesity Research will have full access to the data via openEHR's powerful query mechanism, AQL, which can be used to produce any extract that may be required.

Information Governance and Security

inidus recognise the importance of excellent information governance and security when handling health data and the systems tools and processes are built to meet the highest standards to protect sensitive data.

Standard security feature of the inidus Platform include:

- Hosting in a secure data centre located in England provided by NHS Cloud-hosting experts UK Cloud which meets relevant NHS and Government standards for Information Governance and cybersecurity.
- Secured access via SSL with optional two factor authentication.
- Audit to detect inappropriate access by authorised user.
- Servers and software are maintained to ensure security patches for emerging vulnerabilities are installed and we operate a range of cyber security defence and monitor tools.
- Servers are regularly backed-up to a secondary location.

Support

inidus will provide support to ensure the proper operation of the Registry including the rectification of any software errors and ensuring that the Registry is available for use by UCL Centre for Obesity Research.

We offer an uptime guarantee of 99.5% (measured over any period of 30 days) excluding periods of planned maintenance (these will be notified to UCL Centre for Obesity Research at least 5 working days (9 - 5 Monday - Friday excluding English Bank Holidays) in advance and will not exceed more than a total of 72 hours in any 12 month period), but would expect to achieve higher levels of availability. We continuously monitor the availability of our platform 24/7 and are likely to detect any problems before you do but you may report any issue using the contact details below.

We will undertake to fix any software errors and defects as follows:

Critical errors - Those that render the Registry unusable - With 1 working day

Major errors - Those that interfere with the normal working of the Registry but which don't render it unusable - 3 Working days.

Minor errors - Those of a cosmetic or other minor nature which don't stop the continuing use of the Registry - 10 working days.

Again we would hope to exceed these targets.

Issues should be reported by email to support@inidus.com. We can also be contacted on 03302 231781 during the working day (9 - 5 Monday - Friday excluding English Bank Holidays) However, emails will reach the right people more quickly and may be actioned when the phones are not manned out of office hours.

Costings

Our charges for implementing, hosting and maintaining the proposed Registry are shown in the table below:

Year 1 Costs	
Project Management	£4,750.00
Modelling	£5,560.00
Data entry screens	£5,560.00
Analytics export	£2,500.00
Provision of openEHR CDR	£4,500.00
Total	£22,870.00
Subsequent Years Fixed for 3 years Per annum	
Project Management	£2,850.00
Provision of openEHR CDR	£4,500.00
Model and data entry maintenance	£1,390.00
Analytics export maintenance	£500.00
Total	£9,240.00

These costs are exclusive of VAT which will be added at the prevailing rate.

Year 1 costs include liaison with UCL Centre for Obesity Research to specify and design the Registry to meet their requirements, the required openEHR modelling work, hosting of the openEHR CDR, design and development of simple data entry screens and easy export function. The costs allow for a maximum of 1,000 patients. Charges for additional patients are subject to negotiation but will not exceed £1 per patient per annum.

Year 2 costs include ongoing support for and operation of the Registry and minor changes/maintenance of models, data entry screens and export function. These costs are fixed for 3 years and subject to review thereafter.

Payment Terms

Our payment terms are as follows:

- **30% of Year 1 costs (£6,861.00) will be invoiced on signature of agreement**
- **Remaining 70% of Year 1 costs (£16,009.00) will be invoiced on go-live of service**
- **Charges in subsequent years will be invoiced annually in advance on the anniversary of signature of agreement.**

Invoices are payable within 28 days.

Timetable

inidus will have an initial version of the Registry available for operational use by UCL Centre for Obesity Research within 12 weeks of agreement to proceed.

Appendix A - Replica of UCL Proposal Document

DATABASE

UCL Centre for Obesity Research

Obesity Research Biobank Syndicate (ORBiS)

Potential Versions

- **UCLH Bariatric Centre for Weight Management and Bariatric Surgery**
  - **All patients in the service**
  - **Tier 3**
  - **Patients undergoing surgery**
  - **Clinical Trial (each with separate?)**
- **ORBiS**
  - **Participant Identifier Number allocation**
  - **Tissue storage and analysis details**

Ideally, one master database with each patient having a multi-tabulated profile. Tabs link to pages with all relevant information for a certain topic or clinical trial (see table).

Hospitals

At the outset, most will be in Greater London.

- **UCLH**
- **Whittington Hospital**
- **Chichester**

To be confirmed (study-dependent sites)

- **Homerton Hospital**
- **St George's**
- **Luton & Dunstable**

Once established locally, further regions across the UK may be recruited.

Locations

- **Outpatient clinic – this is likely to be where most data are entered**
- **Wards (peri-operative data)**
- **Research staff computers**

- Laboratory / UCL Centre for Obesity Research (genetics, research findings, tissues received

FIELD	DATA POINT	SOURCE
Demographics	Hospital ID / Patient Identifier Number NHS number Name Age Sex (biological) Gender (as stated by patient) Ethnicity Postcode Occupation Education level Marital status Source of referral (GP/self-referral/secondary care) Funding category (public/self-pay/private insurer)	Hospital records GP letter Case Report Form for studies
Medical History	Comorbidities Expand further for: - Hypertension - Hyperlipidaemia - CVD - Stroke - Respiratory (esp. asthma) - Sleep disorders (esp. OSA) - Cancer - GORD - Liver disease - Arthritis - Psychiatric Hx (esp. Depression) Surgical history Diabetes - T1 or 2/GDM	Hospital records Patient GP letters

	- **Duration** - **Medication** - **HbA1c** - **Diabetic scores (DiaRem/DiaBetter)** **Obstetric & Gynaecological Hx** - **Menstrual: Current menstrual status, LMP, Cycle length** - **Pregnancy: Gravida_Para_, Dates.** *(For male patients, list children + dates)* - **Birth control methods** - **Pregnancy plans for future** - **Hx gynae problems (PCOS, infertility, ovarian disease)**	
Family History	**Obesity** **Bariatric surgery – what was outcome?** **T2D** **IHD/cardiovascular events**	
Drug History	**Medications log** - **Start/stop dates** - **Reason for use** - **Dose + Rx regime**	
Functional status	**Overall assessment (flights of stairs parameter)** **ASA grade** *(?here or in work-up for surgery section)* **Activities of Daily Living** - **Independent or receives care assistance (private/NHS)** - **Mobility level** **Physical Activity** - **Frequency** - **Duration** - **Type of activity**	

Social History	Smoking Hx - Current/Ex/Never - Medium smoked - Dates - Cessation meds Alcohol Hx - Frequency - Volume - Binge frequency Drugs of abuse	
Weight Management History	Weight management - Diets - Exercise programmes - Medications - Tier 3 Date first seen in Obesity Service - T3/4 clinic 1st appointment	Patient Bariatric OP notes
Lifestyle	Eating behaviours Food preferences (Power of Food) Taste and Smell questionnaire Eating disorders	Questionnaires Bariatric OP notes
Bariatric Work-up	Investigations pre-op - Observations/vital signs - Blood tests - Scan reports - DEXA - Bio-Impedance Analysis - OGD +/- H. pylori, histology - Meal test - Functional capacity assessments (STS, 6MWT, Handgrip)	Hospital CDR Bariatric OP notes Peri-operative docs

	- EOSS (Edmonton Obesity Severity Score) - ASA grade	
Bariatric Surgery	Site / hospital Surgeon Operation type Date - Date of surgery - Interval from 1st entry to bariatric service to surgery Length of stay Complications (30-day) Re-admission (30-day) Re-operation (30-day)	Op notes Inpatient records Discharge summary
Bariatric Follow-up	Date of each appointment Who seen Weight loss + BMI measures Key notes on: - Progress - Surgical complications - Medical complications - Eating behaviours Re-operation – when, why, where, what op Re-admission Mortality Follow up investigation results Vitamin/Mineral supplement compliance PROMs HRQoL questionnaires (SF-36, IWQOL-Lite, BDI) Socio-economic outcomes – Return to work *Need to be able to add sections here for each year of F/U, but can keep the form standardised*	Bariatric OP notes Hospital results reporting system Questionnaires

Genetics	Type of sample (blood/saliva) Genotype SNP profile Exome profile Tissues obtained Date +/- expiry date Current location (UCL/RFH) Analysis done (which tests/assays) + results Released to which studies	
Clinical Trials / Research Studies	One tab for each trial patient is entered in to. - BariLifestyle - LiraBariatric - Gravitas - FTO - GOAT - CNS/Taste imaging - HPB imaging	Case report forms for RCT Link to each trial database